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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,790	02/11/2004	Jacqueline C. Timans	DX01040K3B	3044

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,790	TIMANS ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 26-50* is/are pending in the application.

4a) Of the above claim(s) *41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16, 26-31 and 33-40* is/are rejected.

7)☒ Claim(s) *32* is/are objected to.

8)☒ Claim(s) *16 and 26-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/1/04 & 9/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election with traverse of Group V invention and SEQ ID NO:2, represented by the original claims 16-18, filed on 30 November 2006 is acknowledged. The traversal is on the ground(s) that searching four sequences with significant similarity is not burdensome, and that at minimum, SEQ ID NO:6 be rejoined with SEQ ID NO:2 based on the high degree of sequence identity. This is not found persuasive because although the four sequences share sequence similarity, it is impossible to be certain whether a resulting sequence with high degree of sequence identity one query sequence is indeed one of the other claimed sequences. As such, separate searches are required for the each of the two or four sequences, which constitute an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's amendment filed on 30 November 2006 is acknowledged and entered. Following the amendment, the original claims 1-15 and 17-25 are canceled, and the new claims 26-50 are added.

Note, applicants indicate in the instant response that "Group V includes claims 16 and 26-50", which is incorrect because the subject matter of the new claims 41-50 (drawn to a method of modulating an immune response with the polypeptide) is not encompassed by Group V invention (drawn to a polypeptide), nor represented by any of the original claims.

Newly submitted claims 41-50 are directed to an invention that is independent or distinct from the elected invention V for the following reasons: invention V is related to claims 41-50 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for generating the antibody of Invention III.

Currently, claims 16 and 26-50 are pending, and claims 16 and 26-40 are under consideration to the extent that they read on the elected sequence. Accordingly, claims 41-50 are withdrawn from consideration as being directed to a non-elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Formal Matters:

Information Disclosure Statement

Applicant's IDSs submitted on 6/1/04 and 9/13/2005 are acknowledged and have been considered. A signed copy is attached hereto.

Priority acknowledgement

This application claims benefit of U.S. applications 10/000,776 filed on 11/30/01, 09/791,497 filed on 2/22/01 and 09/627,897 filed on 7/27/00, and U.S. provisional application 60/147,763 filed on 8/6/99, which is acknowledged.

Specification

The specification is objected to because the status of U.S. Application 10/000,776, which has been issued as U.S. Patent No. 7,148,300, has not been updated yet.

Claims

Claims 16, 26-32 and 38-40 are objected to for encompassing a non-elected subject matter, SEQ ID NO:4, 6 and 8. The applicant is required to amend the claims to read only upon the elected invention.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is indefinite for the recitation "binds to a cell surface receptor" because neither the claim nor the specification defines the structure of "a cell surface receptor". As such, the metes and bounds of the claim cannot be determined. Claims 35 and 36 are similarly indefinite. Although claim 36 recites the specific term "WSX-1/TCCR", it is an arbitrary name, and is not a recognized name in the art, and thus, is not meaningful as to the structural identity of the molecule.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 26-31 and 33-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to an isolated polypeptide of SEQ ID NO:2 capable of binding to the receptor of SEQ ID NO:12, does not reasonably provide enablement for claims to an isolated polypeptide *comprising* at least 17, 20, 25, 30, 35, 50, or 75 amino acids of SEQ ID NO:2 (claims 16, 26-31 and 40, for example), or % variants of SEQ ID NO:2 (claims 38 and 39, for example), binding to any or all cell surface receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 16, 26-31 and 40 as written encompass a genus of fragments of SEQ ID NO:2; claims 38 and 39 encompass a genus of polypeptides having at least 80% or 90% identity to SEQ ID NO:2, wherein the fragments or variants do not have to have any functional property as there is no functional limitation associated with said polypeptides. While the specification teaches that the IL-D80 polypeptide of SEQ ID NO:2 is a part of IL-27 (IL-D80/EBI3 composite), which is capable of stimulating T cell proliferation (Example XII), and plays a role in driving an inflammatory response (the parent application 09/791,497, page 41, the last two paragraphs), and that IL-27 binds to the receptor polypeptide of SEQ ID NO:12 (page 9, lines 25-27), the specification does not teach any specific fragments or variants as recited, nor biding receptors other than that having an amino acid of SEQ ID NO:12. Further, the specification does not teach the structural and functional relationship of the polypeptide of SEQ ID NO:2, and provides no guidance or working examples as to how to make the functional fragment and variants, or how to use the inactive fragments and variants of SEQ ID NO:2. Furthermore, the skill in the art of the IL-27 is not high as it is a newer cytokine, and does not seem to belong to any previously known cytokine family. Therefore, it is not predictable that any randomly selected fragment or variant of SEQ ID NO:2 meeting the sequence limitation of the claims have the same functional activity or specific antigenicity as that of the polypeptide of SEQ ID NO:2. Furthermore, the claims encompass an unreasonable number of inoperative polypeptides since the claimed polypeptide is not required to have a functional activity, and the specification does not teach a skilled artisan how to use such. Therefore, it would require undue experimentation prior to make and use the invention in a manner commensurate in scope with the claim.

Due to the large quantity of experimentation necessary to generate the infinite number of fragments and variants recited in the claims and possibly screen the polypeptides for

antigenicity/activity, and to determine how to use the inoperative fragments and variants of the polypeptide, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the lack of predictability of the structure of a functional variant, the complex nature of the invention, and the breadth of the claims which embraces a broad class of structurally diverse fragments and variants with or without a functional activity, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 16, 26-31 and 33-40 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a fragment (16, 26-31 and 40, for example), or a % variant (claims 38 and 39, for example) of the polypeptide of SEQ ID NO:2. The claims do not require that said polypeptides possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that are defined only by sequence identity. The specification merely discloses *one* polypeptide of SEQ ID NO:2, which binds to the receptor polypeptide of SEQ ID NO:12, and a few specific variants having SEQ ID NO:4, 6 and 8. No fragments or variants of SEQ ID NO:2 or receptors thereto other than SEQ ID NO:12 meeting the limitation of the claim were ever identified or particularly described.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved in the polypeptide. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of the polypeptides. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 2701 at 2703. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In the instant application, applicants have a polypeptide with a specific function that has not been correlated to any particular structural regions. Therefore, only isolated polypeptide of SEQ ID NO:2, 4, 6 and 8, and the receptor polypeptide of SEQ ID NO:12, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sheppard et al. (US6,822,082) discloses a polypeptide, which amino acid sequence of SEQ ID NO:28 comprises the amino acids 10-242 of the present SEQ ID NO:2 with 85.4% sequence similarity (see computer printout of the search results).

Conclusion:

No claim is allowed.

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, *and* if amended to overcome the objections thereto.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
1/28/07